Shared decision making interventions for disadvantaged populations: systematic review and meta-analysis

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Abstract

Objectives To examine the effectiveness of shared decision making interventions for disadvantaged populations and to determine the critical features of successful interventions.

Design Systematic review, meta-analysis, and narrative synthesis.

Eligibility criteria Randomized controlled trials that assessed the impact of shared decision making training, tools, or programs on patient-centered and clinical outcomes among disadvantaged populations.

Information sources MEDLINE via Ovid, CINAHL, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, PsycINFO and Web of Science from inception to October 2019.

Risk of bias We used the Cochrane Risk of Bias tool, version 2.

Included studies We identified 22 studies that met our inclusion criteria including 6,500 people in Australia, Denmark, or the United States. Twenty studies had overall unclear risk of bias. Seventeen studies included people who met more than one definition of being disadvantaged (race/ethnicity, literacy, education, or income).

Synthesis of the results Interventions were training-based (n=4), audiovisual (n=14), or paper-based (n=4). Audiovisual and training interventions ranged from 2 to 120 minutes. Paper-based interventions ranged from 2 to 33 pages. Thirteen were tailored to the user. In the meta-analysis, interventions improved knowledge (10 studies, standardized mean difference (SMD)=0.51, 95% CI 0.28, 0.77 [I^2=90%, p<0.01]), patient participation (8 studies; SMD=0.25; 95% CI 0.11, 0.38 [I^2=31%, p=0.18]), and informed choice (3 studies, relative risk=2.23, 95% CI 1.24, 4.01 [I^2=83%, p<0.01]). They reduced decisional conflict (4 studies; mean difference=-12.52; 95% CI -23.67, -1.39 [I^2=94%, p<0.01]) and the proportion undecided (4 studies; SMD=0.62; 95% CI 0.43, 0.90 [I^2=6%, p=0.36]). They did not affect anxiety, intention to be screened, or screening behavior. Only 10 studies compared outcomes between those who were or were not disadvantaged. Six found greater benefits for disadvantaged patients. There was no evidence pointing to which intervention characteristics were most effective.

Interpretation This meta-analysis and narrative synthesis provides evidence that shared decision-making interventions for disadvantaged populations can improve knowledge, decisional conflict, patient participation, and informed choice. Due to a lack of data and overall heterogeneity, we could not determine which decision aid features are most effective. Additional research is needed to robustly compare interventions and their outcomes among participants who are disadvantaged to those who are not.

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Introduction

When patients are faced with a healthcare decision where there is more than one available choice, clinical equipoise warrants patient involvement in the decision making process (also called shared decision making).[1] Patient decision aids and decision support interventions are often used to facilitate shared decision making (SDM), shown to improve knowledge and make patients feel more informed.[2] However, there is a risk that SDM primarily benefits those who are more educated, empowered and able to advocate for their needs, while marginalizing disadvantaged groups.[3]

SDM interventions can come in many forms, including paper-based decision aids, computer-based interventions, and clinician or health professional training.[2,4] Each type is likely to provide different advantages and disadvantages to patients who are disadvantaged with respect to race, ethnicity, literacy, education, or income when compared to people who are more advantaged. People from disadvantaged groups, and particularly those with lower literacy/lower health literacy, represent a large proportion of the population in most developed countries. It is estimated that about 36% of Americans have limited health literacy.[5] Australia and countries in Europe report up to 60% of their citizens have inadequate health literacy.[6,7] It is a global problem that affects both developed and underdeveloped countries.[8,9]

In 2014, we published a systematic review and meta-analysis that assessed whether SDM interventions reduced health inequalities.[10] We found that these interventions substantially improved outcomes for disadvantaged groups, and that underserved populations might stand to benefit the most, provided content was tailored to their needs. As the use of SDM interventions is a relatively novel approach, we have updated this 2014 review to incorporate more recent evidence. In order to strengthen our findings, we have also limited our search to only include randomized controlled trials and expanded our definition of a disadvantaged group using published definitions whenever available.[11,12] Additionally, we have used an adapted version of the TiDIER checklist to identify the attributes of SDM interventions that could best support disadvantaged populations.[13] We had three aims in the context of this review:
(1) assess if SDM interventions improved outcomes for disadvantaged groups,
(2) assess if SDM interventions decreased health inequalities, and
(3) determine the critical features of the included interventions that best support SDM for disadvantaged populations.

Methods

Protocol and registration

We revised and re-registered the 2012 protocol through PROSPERO to outline the objectives and methods of this systematic review in October 2019 (CRD42012002200).[10] We planned and reported this review following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) and the Cochrane Handbook for Systematic Reviews of Interventions.[14,15] See supplemental file 1 for the completed PRISMA checklist.

Inclusion criteria

We included manuscripts reporting results of randomized controlled trials that assessed the effect of SDM interventions on disadvantaged groups and/or health inequalities. We included cluster designs. At least 50% of the participants needed to be from a disadvantaged group, except if a separate analysis was conducted for this group. We defined a disadvantaged group as meeting one or several of the following criteria, based on the author's description:

1. People who are socially disadvantaged with respect to poverty or lower socioeconomic status
2. People who are socially disadvantaged as a result of their ethnicity or race
3. People who have lower educational attainment (no college degree)
4. People who have lower literacy and/or lower health literacy
5. People who are socially disadvantaged with respect to geographical location (areas described as disadvantaged and/or medically underserved)
6. People who are uninsured or on public health insurance
7. People who have lower numeracy
8. People who are socially disadvantaged as a result of speaking a primary language that differs from the official language(s) of their country of residence

We had no language restrictions. We included all conditions and clinical settings (e.g., lay care, primary care, secondary/tertiary care). We defined SDM interventions as interventions or strategies designed to engage patients in medical decision-making and/or facilitate SDM, patient involvement in medical decision-making, or patient activation. This included decision aids, physician coaching, patient coaching, skills workshops, and patient prompts, provided the aim was to increase patient engagement in decision-making. Educational or self-management interventions that exclusively targeted knowledge or behavioral change were excluded from the review. However, we included educational or self-management interventions that targeted activation and involvement in medical decision making, as well as knowledge. We did not require that studies report specific outcome measures. Specific outcome measures of interest to SDM research were prespecified including knowledge, decisional conflict, decision quality, patient participation, proportion undecided, satisfaction, anxiety, choice, and quality of life. We allowed multiple definitions of a control group, as long as there was a group not exposed to the tested intervention.

Search strategy and study selection

We adapted our search strategy from the 2014 review, consulted a Dartmouth research librarian, and piloted it in MEDLINE via Ovid (see supplemental file 2, figure 1). We searched MEDLINE via Ovid, CINAHL, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, PsycINFO and Web of Science from inception to October 2019. Our search themes included "Decision making/Health communication", "Decision aids/Patient education", and "Disadvantaged Populations". The disadvantaged populations theme included search terms focused on criteria for being disadvantaged listed above. We limited our searches to randomized controlled trials and excluded all pilot trials. We hand-searched the reference list of all primary and review articles. We also performed a ''cited by''

and ‘‘related articles’’ search through PubMed. We also put our search terms into Google Scholar and one reviewer looked at the first 100 hits to check for any relevant records not already captured. We also included all randomized controlled trials already reported in the 2014 review if they were not captured using the methods detailed above.

Using Rayyan, researchers independently screened the title and abstract of retrieved records (two per record: RWY, M-A D, SS, LPP, GE, JE) and the full-text of articles meeting inclusion criteria during title/abstract review (two per record: RWY, M-A D, JE).[16] We resolved disagreements as a team.

Data extraction and risk of bias assessment

Six researchers conducted independent double data extraction using a pre-designed, piloted form adapted from previous reviews (two per record: RWY, M-A D, JE, SS, LPP, JM).[10,17] We extracted information about the 1) author(s), (2) publication year, 3) country, 4) study aims, 5) setting, 6) medical condition/field, 7) participant characteristics and sample size, 8) outcome measures and methods of analysis, 9) intervention characteristics, 10) control condition, and 11) follow up. We detailed the intervention characteristics using an adapted version of the Template for Intervention Description and Replication (TIDieR) checklist.[13] Six researchers used the Cochrane Risk of Bias tool (version 2) to assess the risk of bias for all included studies (two per record: RWY, M-A D, JE, SS, LPP, JM).[18]

Data synthesis and analysis

We adapted our data synthesis methodology from the 2014 review.[10] We pooled studies in a meta-analysis for outcome measures that were reported at least three times across the included studies. All analyses were done in R.[19,20] For studies with more than two groups, we analyzed the groups that were closest to a control and SDM intervention. If there were several interventions being evaluated, only SDM interventions were included. We calculated the weighted treatment effect and 95% confidence intervals for all outcomes. We used a random-effects model to account for the assumption that the included studies did not come from the same population.[21] We used Hedges’ method to calculate all pooled estimates.[22] We also conducted sensitivity analyses for each outcome with significant findings in the meta-analysis using the Hartung-Knapp method given the varying study sizes and heterogeneity across the included studies.[23–25]

We conducted a narrative synthesis to assess the interventions’ effect on health inequalities, to determine the critical features of included interventions, and for all outcomes that could not be included in the meta-analysis. This synthesis was guided by the UK’s Economic and Social Research Council (ESRC) Methods Program.[26] We combined the evidence by looking at the outcomes and heterogeneity of the included studies to compare and contrast the combined results.

Measure of treatment effect for the meta-analysis
For continuous outcome measures, we calculated effect sizes using standardized mean difference (SMD) using Hedges' g method when the tools for outcome measurement varied.[21] We calculated effect sizes using mean difference (MD) when the outcome measurement tool was the same across studies. If measures were repeated, we selected the time point that was the most conservative estimate to understand the interventions effect on the outcome. For studies that reported outcome measures as a proportion, we calculated a relative risk.

Dealing with missing data
If standard deviation data were not provided, we used calculation methods in the Cochrane Handbook to determine standard deviation using p-values, standard errors, or 95% confidence intervals.[27] We excluded studies from the meta-analysis that did not report outcomes in sufficient detail. If this occurred, they were still included in the narrative synthesis.

Assessment of heterogeneity
We used the I^2 statistic to determine the level of heterogeneity for each calculated effect estimate and assumed an I^2 of greater than 50% and p-value of less than 0.05 to indicate significant heterogeneity. For studies or outcomes included in the narrative synthesis, we looked at study quality, outcome measurement, and intervention differences to assess heterogeneity.[26]

Assessment of reporting bias
We used funnel plots to visually assess for potential publication bias for each outcome included in the meta-analysis.[15] Publication bias was assessed quantitatively using Egger's regression test for asymmetry for outcomes reported by at least 10 studies.[28] A p-value of less than 0.05 indicated significant publication bias.

Subgroup and sensitivity analysis
We did not prespecify any subgroup or sensitivity analyses. However, several arose as a result of our findings during data extraction. All studies reporting decisional conflict used either the original Decisional Conflict Scale or the low literacy Decisional Conflict Scale.[29,30] We therefore conducted a subgroup analysis for decisional conflict based on the type of scale used. Additionally, we conducted two additional sensitivity analyses based on the results of our risk of bias assessment with outcomes that had at least five studies included in the meta-analysis. We determined whether risk of bias in the randomization of participants and deviations from the intended interventions affected the results of all outcomes. Finally, we used the Cochrane standard deviation calculator for a proportion of the studies in the knowledge and patient participation meta-analyses. Therefore, we conducted sensitivity analyses to see if the results changed when the calculator was used.

Critical evaluation of included interventions
We summarized the characteristics of the included interventions, stratified by whether the outcomes tested for that intervention did or did not favor its use.[13]

Patient and public involvement

A patient partner previously involved in our work joined us as a team member for this study (MM). She helped us develop the search criteria, has reviewed the protocol and is an author on this manuscript.

Results

Identified studies

We retrieved 1,724 records from the database searches and 43 from additional search methods. After removal of duplicates, we screened the title and abstract of 1,366 records and later reviewed the full text of 56 articles. Twenty articles fully met our inclusion criteria after data extraction. We added two articles from the 2014 review not captured in the new search, including 22 articles in this review (figure 1).

Figure 1. PRISMA flow diagram

Five studies included more than one intervention group.[31–35] Two studies combined the intervention groups for analysis so all outcomes reported in this analysis use the combined outcomes of the two intervention groups.[33,34] Two studies had interventions that targeted clinicians.[31,36] In order to isolate the effect of the patient-facing intervention, we only reported data from the arms that focused on patient interventions. For the study by Kripalani and colleagues, we selected the intervention closest to a decision aid (patient education handout).[35]

Study and participant characteristics

Of the 22 included studies, 19 were based in the United States, two in Australia, and one in Denmark. Total number of participants ranged from 43 to 986, an average of 296 patients. Eleven studies focused on screening behavior, nine were associated with treatment options for various health conditions, and two were about advanced directives and care planning. Seventeen of the studies had greater than 50% of participants from racial or ethnic minorities, an additional one targeted minority groups but did not reach the 50% threshold. Eight studies had greater than 50% of participants with lower annual household income. The cutoff for being considered lower income varied across studies. However, on average, low income participants had an annual household income of less than $27,400. Twelve studies had greater than 50% of participants with lower education (less than a bachelor's degree), the majority of participants from seven of these studies had a high school education or less. Four reported that more than 50% of participants had lower health literacy based on the measure of health literacy used in the study, with an additional three stating they targeted lower literacy or lower health literacy populations. Thirteen of the 22 studies had a majority of participants meet more than one criteria for being considered disadvantaged. Table 1 includes a list of study characteristics.

Table 1. Select study and participant characteristics

Description of included interventions

Across the studies, four interventions were training or group discussions with no tested visual component. Four were paper-based interventions, one of which also had an accompanying DVD. Fourteen were virtual, computer- or web-based interventions (table 2). Of these, 11 were interactive (e.g, being able to select specific options or alter the path through the intervention) and three were static (e.g., videos only or click-through design). Among the virtual and training interventions, the average time to use the intervention ranged from 41 to 51 minutes (range 2 to 120 minutes). One intervention was given to patients to use repeatedly and averaged 6 uses per week for 13 minutes per use over 26 weeks.[37] Among the paper-based interventions, one was short (2 pages) and the remaining three were 20-33 pages long). Five reported readability scores which ranged from fifth to tenth grade.

Thirteen of the interventions were delivered before a specific clinic visit, two were delivered after a specific clinic visit, five were delivered independent of a specific clinic visit, one was delivered both before and after, and one study did not report when the intervention was delivered.

The majority (n=18) of interventions were used by or delivered to participants only once. For interventions delivered in the home, the exact number of times used could not be determined. Thirteen of the interventions had components tailored to the participant which could have included incorporating medical details or patient preferences into the intervention.

Table 2. Characteristics of the included interventions
*Intervention characteristics pulled from the published protocol or other publications on the tool.[38–41]

Risk of bias in included studies

A large majority of the included studies had overall unclear risk of bias (20/22, figure 2). The reason varied across studies but the largest two domains for unclear risk of bias were due to outcome measurement (13/22) and reporting results (15/22). Risk of bias due to outcome measurement typically occurred because of insufficient information about blinding of the outcome assessors. Risk of bias due to reporting results typically occurred because information on a protocol or trial registry was lacking, or disagreement between the published study and published protocol or trial registry. The domain with the most studies having low risk was risk of bias due to randomization procedures (13/22). The domain with the most studies having high risk of bias was risk of bias due to deviations from the intended interventions (5/22). Studies were typically given this rating because there was no blinding of participants or researchers delivering the interventions.

Figure 2. Risk of bias for the included studies

Meta-analysis

Knowledge

Fifteen studies reported knowledge as an outcome measure.[32–34,42–53] Ten studies reported these as a continuous outcome and were included in the meta-analysis. Two studies measured knowledge more than once post-intervention.[45,47] For these studies, the longest follow-up time point was used in the meta-analysis. One study reported knowledge results as dichotomous and four did not report the knowledge results with sufficient information to be pooled into a meta-analysis.[32,33,51–53]

In the meta-analysis, the pooled standardized mean difference was 0.51 (95% CI 0.28, 0.77). There was substantial heterogeneity (I^2=90%, p<0.01). See figure 3. The sensitivity analysis using the Hartung-Knapp method did not affect this outcome substantially. When looking at the studies by risk of bias due to randomization methods, the pooled estimate for studies with low risk of bias remained significant. When looking at studies by risk of bias due to deviations from the intended interventions, only two studies had low risk of bias. Their pooled estimate was not significant. When we performed a sensitivity analysis based on whether the Cochrane standard deviation calculator was used, the estimates for both groups remained significant. See supplemental file 2, figures 2-5 for the forest plots of all sensitivity analyses.

Among the five studies not included in the meta-analysis, three reported no significant differences in knowledge at the longest follow-up time point,[32,51,53] and two reported significant differences in knowledge favoring the intervention.[33,52]

Decisional conflict

Ten studies reported decisional conflict as an outcome, all as a continuous outcome measure.[33,34,44–49,51,53] Three studies did not report their decisional conflict data in sufficient detail to be included in the meta-analysis.[33,47,51] Heisler and colleagues (2014) measured decisional conflict at two time points. We selected the longest follow-up period (three months) to maximize the potential for decisional conflict to occur.[45]

When pooling all seven studies, the standardized mean difference was -1.31 (95% CI -3.19, 0.57), with significant heterogeneity (I^2=99%, p<0.01). See figure 4. When looking at the studies by risk of bias due to randomization or deviations from the intended interventions, there were no changes to statistical significance. See supplemental file 2, figure 6-7.

When we subgrouped the studies by scale (original decision quality scale versus low-literacy decision quality scale), the pooled mean difference for studies using the original scale was -1.64 (95% CI -3.30, 0.03) with no heterogeneity (I^2=0%, p=0.44). See figure 4. The mean difference for studies using the low literacy scale was -12.52 (95% CI -23.67, -1.39), with significant heterogeneity (I^2=94%, p<0.01). The pooled mean difference in the sensitivity analysis using the Hartung-Knapp method was -12.53 (95% CI -30.20, 5.13). See supplemental figure 8.

Among the three studies with insufficient information for inclusion in the meta-analysis, none had significant differences between the intervention and control groups at their latest follow-up time point.[33,47,51]

Patient participation

Eleven studies reported patient participation in care as an outcome.[31,32,34,36,37,43,46,49,53–55] Patient participation in care included multiple definitions: SDM, patient preferences for level of involvement in care, patient perceptions of involvement in their care, patient self-advocacy, and patient-centered communication. Two studies measured patient participation from different perspectives (patient, provider, observer).[31,49] For these studies, we only used the patient measure of participation. Gustafson and colleagues (2001) measured participation more than once; we used the time point closest to when the intervention was used to isolate the effect of the intervention on participation.[37] Three studies did not report their outcome related to patient participation with enough detail to include in the meta-analysis.[32,34,36]

The pooled standardized mean difference for the eight studies included in the meta-analysis was 0.25 (95% CI 0.11, 0.38). Heterogeneity was not significant (I^2=31%, p=0.18). See figure 3. The sensitivity analysis by risk of bias due to randomization, deviations from the interventions, or using the Hartung-Knapp method did not affect this outcome substantially. When we performed a sensitivity analysis by whether the Cochrane standard deviation calculator was used, only the estimates for the group where standard deviations were calculated was significant (estimate=0.23, 95% CI 0.14, 0.33 versus estimate=0.33, 95% CI -0.25, 0.91). See supplemental file 2, figures 9-12 for sensitivity analyses. For the three studies that did not report patient participation with enough detail for inclusion in the meta-analysis, one intervention improved patient participation in care compared to the control group.[34]

Anxiety

Six studies measured patient anxiety,[34,43–45,52,55] four of which had usable data for the meta-analysis.[34,44,45,55] In the meta-analysis, the pooled standardized mean difference was -0.08 (95% CI -0.30, 0.03) with low heterogeneity (I^2=42%, p=0.16). The two other studies measuring anxiety reported no differences between the control and intervention groups.[43,52] See figure 3.

Proportion undecided

Five studies reported whether participants were undecided about their treatment/screening approach.[42,43,49–51] One did not report data in sufficient detail for the meta-analysis.[43] In the meta-analysis, the pooled relative risk was 0.62 (95% CI 0.43, 0.90) with low heterogeneity (I^2=6%, p=0.36). See figure 5. In the sensitivity analysis using the Hartung-Knapp method, significance was lost (relative risk: 0.62; 95% CI 0.33, 1.16). See supplemental file 2, figure 13.

Informed choice

Five studies measured whether participants made an informed choice.[34,42,44,49,52] Three reported data in sufficient detail for inclusion the meta-analysis.[34,49,52] In the meta-analysis, the pooled relative risk was 2.23 (95% CI 1.24, 4.01). This indicates that participants in the intervention arms were about two times more likely to make an informed choice. Heterogeneity was substantial (I^2=83%, p<0.01). See figure 5. In the sensitivity analysis using the Hartung-Knapp method, significance was lost (relative risk: 2.23, 95% CI 0.59, 8.33). See supplemental file 2, figure 14. For the two that did not report their results with enough detail, one found that there was greater informed choice in the intervention arm,[42] and one did not.[44]

Screening behavior

Given the large number of studies related to cancer screening, we looked at additional outcomes related to screening including whether screening tests were ordered or screening was completed. Among the ten studies related to cancer screening, four studies measured intent to undergo screening.[42,43,46,52] In the meta-analysis, the relative “risk” was 1.03 (95% CI 0.97, 1.09) with limited heterogeneity (I^2=35%, p=0.20). See figure 6. Seven reported outcomes related to ordering or completing screening,[33–35,42,44,46,56] all for colorectal or prostate cancer. Two studies reported both testing ordered and testing completed.[46,56] We conducted one meta-analysis each for screening ordered and screening completed. The relative “risk” was 1.60 (95% CI 0.75, 3.43) for screening ordered and 1.07 (0.85, 1.34) for screening completed. Heterogeneity was substantial for both, I^2=71% (p=.02) and I^2=86% (p<0.01) respectively. See figure 6. One study did not report this outcome with sufficient detail for inclusion in the meta-analysis.[33] It found no differences in screening behavior between arms.

Publication bias

For knowledge, the only outcome where ten or more studies reported data, the Egger’s regression indicated there was not significant publication bias (p=0.61). We observed publication bias when examining the funnel plot for decisional conflict and patient participation with a lack of symmetry around the pooled effects. The funnel plot for decisional conflict had larger studies concentrated around larger effect sizes with fewer small studies with larger effect sizes. The funnel plot for patient participation lacked smaller studies with neutral or negative effect sizes on patient participation. We did not observe publication bias when examining the funnel plots for anxiety, proportion undecided, treatment intent, or screening behavior. Funnel plots are in figure 7.

Narrative synthesis

Treatment or screening choice

Six studies measured whether a specific choice was made for screening (e.g., stool test vs. colonoscopy for colorectal cancer screening) or treatment (e.g., mastectomy vs. lumpectomy for breast cancer treatment).[47,48,50,51,55,56] The measures and findings for these outcomes were highly heterogeneous and could not be pooled into a meta-analysis. Five of the studies found that participants in the intervention arm had statistically significant differences in treatment or screening choice,[36,48,50,51,55] one found no differences.[47]

Effect on health inequalities

Ten studies reported findings that compared the effect of the intervention in the context of being disadvantaged.[31,33,37,44,49,52–56] Six found that their interventions were statistically more effective among disadvantaged participants, based on ethnicity, lower education, lower literacy, or lower income.[31,37,49,52–54] Four found that while there were significant differences in outcomes between intervention and control groups, this did not change when stratifying by disadvantaged status.[33,44,55,56]

Other clinical outcomes

Four studies measured at least one clinical outcome not included in the meta-analysis including: blood pressure, hemoglobin A_{1C}, medication adherence, depression.[32,36,45,55] Three studies saw no differences in clinical outcomes, while one by Boulware and colleagues (2019) found that blood pressure improved for patients receiving a 20-30 minute SDM training more than patients in the control group.[32]

Other outcomes

Two studies reported decision satisfaction as an outcome, neither of which reported any differences between the control and intervention groups.[34,51] One study reported decision quality as an outcome but could not analyze their results due to ceiling effects.[47] One study measured quality of life and found no significant differences.[37] Two studies measured attitudes towards screening and found no differences.[44,46] Two studies reported outcomes related to self-efficacy,[45,47] one found that self-efficacy improved more in the intervention group.[47] Two studies measured whether a screening discussion occurred with a clinician post-intervention, both of which found significantly higher numbers of screening conversations in the intervention group.[35,42]

Perceptions of the interventions

Nine studies reported outcomes related to perceptions of the intervention tested in the trial. All found that the interventions were rated positively at some level. However, there were substantial variations on the measure used and whether or not it was compared to the control group. Six measured *helpfulness or utility* of the intervention,[34,47,50,52,53,55] and all six found the intervention was rated as helpful. One found this was statistically different when compared to the control group.[55] Four measured *ease of use*, which was high for three of the

studies.[34,47,55] In one study, only 51% rated the intervention as easy to use but this was significantly higher compared to the control group.[49] Three measured whether information seemed *balanced*,[33,34,52] all three found that it was when compared to a control group however this was only statistically significant in two.[33,52] Three measured *clarity/understanding* of the interventions. Two found it was high regardless of arm,[34,52] one found it was higher in the intervention arm.[49] Three found that participants *would recommend* the tool to others,[50,52,53] one found this was higher in the intervention arm.[53]

Characteristics of successful interventions

Across all studies, there was limited evidence on which interventions were more effective at promoting SDM. From the eleven studies that reported outcomes related to patient participation and shared decision making,[31,32,34,36,37,43,46,49,53–55] five improved SDM.[34,43,46,54,55] Among these five, three were computer-based, one was paper-based, and one was training-based. Intervention length ranged from 20 to 120 minutes. Three were delivered before the clinic visit and two were independent of a clinic visit. Three were tailored to the participant and two were not. Readability was not reported for most interventions.

Across the studies that analyzed their results by disadvantaged studies, from the six that saw greater benefit for those who are disadvantaged,[31,37,49,52–54] four were computer-based, one was paper-based, and one was training-based. Three were delivered before the clinic visit, two were independent of a clinic visit, and one was delivered before and after. Four were delivered at the clinic and two were delivered at home. Three were tailored to the participant and three were not.

Discussion

Summary of main findings

In this meta-analysis of shared decision-making interventions targeting disadvantaged populations, we found that the interventions significantly improved knowledge, patient participation in care, and informed choice. They also reduced decisional conflict and the proportion of people undecided. They did not have an effect on anxiety, whether or not people intended to get screened, had screening tests ordered, or received screening.

In the narrative synthesis we found that the interventions influenced treatment choice and increased the likelihood of a screening discussion occurring with a clinician. There were no differences in reported clinical outcomes, satisfaction, attitudes, or self-efficacy. When measured, participants found the interventions helpful, easy to use and balanced. There was significant heterogeneity when looking at the key features of the interventions and no single feature or set of features led to improved outcomes.

Among the ten studies that included an analysis of outcomes based on being disadvantaged, over half found that their interventions were more successful among those who were

disadvantaged. However, there was no evidence on the intervention characteristics that are most successful at supporting SDM for all or for disadvantaged populations.

Strengths and limitations

Strengths and limitations of the included studies

The articles included in the review were all randomized controlled trials, with an active control group. There were over 6,500 participants across the studies including 3,300 receiving an intervention and an average of about 300 participants per study. All studies had participants who met at least one condition for being considered disadvantaged but more than half had participants who met more than one condition including five that met two conditions and seven that met three conditions. The included interventions had a wide range in format, but no one intervention type stood out as most effective, indicating many different intervention types might be effective to support decision-making in disadvantaged populations.

A large number of studies had an overall unclear risk of bias. This was often because there was not enough information in the article about blinding of the study personnel or prespecified primary and secondary outcomes. Additional information on these methods might have indicated lower or higher overall bias. The range in included interventions and controls could also be seen as a limitation because of the heterogeneity this might have introduced. Finally, the overwhelming majority of the studies included in this analysis were from the US and all included studies were from wealthy countries.

Strengths and limitations of the review method

By limiting our review to interventions only tested through randomized controlled trials, we built on and strengthened the meta-analysis conducted in 2014 by Durand and colleagues.[10] The 2014 review included seven randomized controlled trials compared to the 22 in this analysis. Also, in this review we used the newest version of the Cochrane Risk of Bias tool, strengthening the assessment of risk of bias in our study. We also included a critical appraisal of the included interventions using the validated TIDieR checklist. We adhered to the highest levels of data creation for a systematic review including consulting a research library to develop our search strategy and conducting dual independent review at each phase of data collection.

Our limitations include that we did not reach out to authors to collect unreported data, instead reporting it as missing or using the Cochrane calculator where appropriate. We conducted a sensitivity analysis using the Hartung-Knapp method to calculate the weighted treatment effect when weighted effect was significant in the primary analysis. This was a strength of the method but showed that some results were sensitive to this emerging analysis approach. Due to the nature of the included studies, there was substantial heterogeneity for some of our findings so we must take this into account when interpreting our findings.

Comparison with other studies

Our findings support and strengthen the conclusions from Durand and colleagues' 2014 study regarding knowledge, informed choice, and patient participation. That review asked the same question but did not limit their search to randomized controlled trials. This meta-analysis also supports the findings in Stacey and colleagues' review (2017) looking at all decision aids, not just those targeted at disadvantaged populations. Their review also found similar differences in knowledge, informed choice, anxiety and decisional conflict. They had enough studies to find significant reductions in people having prostate-specific antigen testing but also found no significance for other screening decisions. Notably, Stacey and colleagues' review (2017) includes 105 studies, almost five times the amount of studies included in our review, while limiting their search specifically to decision aids rather than all decision-making interventions as we did. While this analysis is robust with important findings that can inform future work, we believe more research is needed on interventions for disadvantaged populations in rigorous randomized controlled designs. There is a lack of evidence demonstrating the effectiveness of decision-making interventions among disadvantaged people compared to non-disadvantaged people.

Implications for research and clinical practice

Our findings suggest targeted interventions might help narrow the wide gap in care experienced by disadvantaged populations. The differences in how people who are disadvantaged receive care have been well documented.[57,58] These differences are compounded by the likelihood that disadvantaged populations are less likely to seek out health information.[59,60] We need additional research on how these interventions narrow the gap not just on outcomes such as knowledge but longer term outcomes such as decision satisfaction, patient participation, and even clinical outcomes such as surgery or treatment choice. National policy in recent years has highlighted the need for improvements in patient-centered care with only some discussion on how this shift might affect populations differently depending on their background, literacy, or socioeconomic status.[61–63] The IPDAS criteria and the SUNDAE (Standards for UNiversal reporting of patient Decision Aid Evaluation) checklist for reporting decision aids included ensuring that a decision aid is written in plain language but being a disadvantaged recipient of a decision-making intervention can be more complex than literacy level.[64,65] Redefining how policymakers and researchers think about what it means to be disadvantaged in a complex healthcare system will help us create and implement interventions that are appropriately able to change the care this population receives.

Conclusions

This updated review shows strong evidence that decision-making interventions for disadvantaged populations can improve outcomes related to knowledge, decisional conflict, patient participation, and informed choice. However, this review did not reveal what intervention characteristics best support disadvantaged populations. Despite the evidence presented here, the development of tailored, effective interventions for disadvantaged populations is not keeping

up with the broader trajectory across the world focused on the development of decision-making interventions. It is critical to continue to use the interventions that have proven to be effective and develop or adapt new interventions that ensure people who are disadvantaged can benefit from their use.

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Conflicts of Interest

None for LPP, JE, JM, RWY.

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